

viedoc™

Release Notes

Viedoc 4.74

Planned for 2023-02-28

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List of functionalities that have been added and updated in this release.

New and updated functionality

Viedoc eTMF

- Viedoc eTMF now has added support for versions 3.2.0 and 3.2.1 of the TMF reference model.
 - Viedoc eTMF supports templates that include a sheet with 3.1.0, 3.2.0, or 3.2.1 in its name.
 - In TMF Admin, the initial value of the TMF reference model is based on the version in the instantiated structure. In maintenance mode, the eTMF Manager can now change the version of the supported TMF reference model. Changes to the TMF reference model version are displayed in the Structure changes window and listed in the complete audit trail report.
 - The TMF Archive now has added support for versions 3.2.0 and 3.2.1 of the TMF reference model.
- In the Trial Master File view, the Details page now has an option to save a customized selection of columns, including their positions, width, filters, and sort order. The customized selection is specific to each user.
- In the Trial Master File view, some enhancements to the document search have been introduced. Now, when a user performs a search on the Structure page, it displays the search results with the Default option. If the user performs any further search on the Details page, it displays the search results with the Customized option if the user has saved a Customized option. If the user has changed the current filter or column settings of the Default or Customized option and then performs any further search, the search results are displayed with the current Default+ or Customized+ option. If a user performs a search on the Details page, the search results are displayed with the Default option, unless the user has saved a customization. If a user deletes the search string from the search field, the previous option (Default, Customized, Default+, or Customized+) is displayed.
- In the Trial Master File view, the document preview now displays more information for zipped folders. The following is displayed: Icon + filename, date modified (in the format YYYY-mm-DD HH:MM), type, and size in kB.
- In the Trial Master File view, the Details page now includes the columns Milestone and Milestone group.
- In TMF Admin, when maintenance mode is on, the eTMF Manager can now edit the name and the version of the instantiated structure. The name change is displayed in the Structure changes window and listed in the complete audit trail report.

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List of new and updated functionalities continues.

Viedoc Designer/PMS studies

- In Viedoc Designer, the Study settings for Japanese PMS studies now include a new option: Partial Submit Setup. Enabling a Partial Submit allows the designer to configure which forms will be able to be submitted individually. Site/clinic staff and the sponsor can then manage individual forms that is, submit/receive/return/review/report forms, before all the data in the booklet is completed. Any form in use from the current design can be selected. By default, Partial Submit Setup is disabled. The default behavior, if Partial Submit is disabled, is that only AE forms can be submitted/received/returned/reviewed/reported individually.
- After selecting a form to be partially submitted, the following settings can be configured for the Partial Submit Definition for the form:
 - Mark the form as an Adverse Event. This allows clinic or sponsor side users to differentiate between the partially submitted forms that are Adverse Events and the ones that are not.
 - Set an optional JavaScript condition that must be TRUE for clinic users to be able to submit the form individually.
 - You can also customize the notification messages to be shown on the clinic side or on the sponsor side for each Partial Submit Definition.
- In Viedoc Designer, for Japanese PMS studies only, the Partial Submit Setup configuration can be viewed in a separate sheet in the Complete Configuration report of the study design. The Complete Configuration report Excel file contains the following information:
 - If the Partial Submit Setup is enabled.
 - A list of the forms which can be submitted individually, as well as any conditions set for the form.
 - Clinic and Sponsor side notification messages.
 - If the form is marked as an Adverse Event.
- The Abbreviated Configuration report shows whether the Partial Submit Setup is enabled, and lists the existing partial submit definitions.

Viedoc Admin/Clinic/Designer/TMF/Viedoc Me/Logistics/Reports

- On the Chinese instance/region, the title on all webpages have been appended with Viedoc X | Viedoc EDC 电子数据采集系统, where X is Admin/Clinic/Designer/TMF/Viedoc Me/Logistics/Reports.
- On the French and Japanese instances/regions the title is Viedoc X, where X is Admin/Clinic/Designer/TMF/Viedoc Me/Logistics.

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List of new and updated functionalities continues.

Viedoc Web API

- Updates to the Viedoc Web API considered as breaking changes will always be introduced in a new API version only. To ensure backward compatibility is maintained, the API version must be specified. If the API version is not specified, the latest available version will be used. Different versions can be specified at endpoint level. As of this release, there is only one API version available.

Viedoc Reports

- In Viedoc Reports, the SampleReportCode.R file contains a new sample code on how to manage local variables in R.
- Viedoc Reports now supports the survival package of R for custom reports.

Viedoc Coder

- We've enhanced and improved the user interface for displaying coding items in Viedoc Coder. You can resize columns and copy text from two columns with additional values and paste them into the dictionary search field.xxxx

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Bug fixes



List of bug fixes that have been updated in this release.

This section lists the bugs that were solved in this release. For each bug, it describes the following:

- **Affected area(s):** describes briefly which area(s) of Viedoc the bug is related to, so that it is easy to identify if any of your active studies are affected.
- **Bug description:** explains the issue and/or how it was solved. In case there are consequences for existing data, this is clearly mentioned in a “Note!”.

The following corrections have been implemented in the Viedoc 4.74 release:

- **Affected area(s):** Viedoc Clinic
Bug description: When clearing an item value during the same form editing session, so it was first hidden and then became visible again, the reason given was “Removed due to data dependency” with the “System” as the user. This is now solved so that a reason for the change must be provided, and this reason and the user ID and username will be listed in the audit trail records.
- **Affected area(s):** Viedoc Clinic, Viedoc Admin
Bug description: When a new site was added to a study with the study design set to become effective on a future date, clinic users could not be invited to the site. User roles could be selected but not the site. This is now solved.
- **Affected area(s):** Viedoc Clinic
Bug description: On the Selection page, in the Issues view, for forms with issues, the issues list displayed forms with issues, for example queries, which should have been hidden for users due to role visibility conditions. Users could not select to open the form or view the item or item group if the form was opened but could view the text in the query. This is now solved.
- **Affected area(s):** Viedoc Clinic
Bug description: Formatting an upgrade notification message for a revised study design with curly brackets {} prevented the Messages pane on the study start page from opening. This is now solved.
- **Affected area(s):** Viedoc Clinic
Bug description: When resetting an unscheduled event containing form(s) set as hide always, an error message was displayed, “Error: There are forms in this event”. This meant that the event could not be reset/deleted because of the auto update hidden form in the event. This is now solved so that hidden forms will now be automatically deleted if the event is reset.

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List of bug fixes continues.

- **Affected area(s):** Viedoc eTMF
Bug description: In the TMF Admin view, when renaming the instantiated template, that action was listed as duplicate entries in the complete audit trail report. This is now solved.
Note! If you have archived an incorrect audit trail report before the release of Viedoc 4.74, you might want to regenerate it to make sure the archive is correct.
- **Affected area(s):** Viedoc eTMF
Bug description: In the TMF Admin view, when editing a newly added artifact before applying the Add artifact changes to the active structure, the action was incorrectly listed as an Edit artifact action in the complete audit trail report, instead of the edits being part of the Add artifact action. This is now solved.
Note! If you have archived an incorrect audit trail report before the release of Viedoc 4.74, you might want to regenerate it to make sure the archive is correct.
- **Affected area(s):** Viedoc eTMF
Bug description: In the TMF Admin view, when an ongoing template upload was cancelled, the template was in some cases still uploaded. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: In TMF Admin, when adding a milestone with the same ID or name (or both of those properties) as for an existing milestone (active or deleted), an error would occur, and the validated fields were not highlighted. Likewise, when editing a milestone and changing the ID or the name (or both of those properties) to the same value as an existing milestone (active or deleted), an error would occur. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: In TMF Admin, when editing an artifact in maintenance mode, the Save button was in some cases not available. And, vice versa, in some cases, the Save button was incorrectly shown when the artifact properties were not changed, compared to the properties in the active version of the artifact. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: In TMF Admin, in maintenance mode, if a zone, section, or artifact was edited and saved, then edited again back to the initial value and saved, the zone, section, or artifact was sometimes marked red, even though no changes had been made. Also, the button Apply changes was enabled, and when clicking on it, a pop-up window showed that the zone, section, or artifact had been edited. Furthermore, the complete audit trail report incorrectly showed that there had been a change to the zone, section, or artifact. This is now solved.
Note! If you have archived an incorrect audit trail report before the release of Viedoc 4.74, you might want to regenerate it to make sure the archive is correct.
- **Affected area(s):** Viedoc eTMF
Bug description: In TMF Admin, when changes to the structure had been made and applied, it wasn't possible to delete the instantiated template, and an error message was displayed. This is now solved.

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List of bug fixes continues.

- **Affected area(s):** Viedoc eTMF
Bug description: In some cases, the structure name was truncated, compared to the template name. This is now solved, so that the structure name is the same as the template name.
- **Affected area(s):** Viedoc eTMF
Bug description: In the Trial Master File view, if a zone and section had been deleted, they were not removed from the Structure page while performing a “Save changes” action. To be able to see the updated structure, the page had to be refreshed. This has now been solved.
- **Affected area(s):** Viedoc eTMF
Bug description: In the Trial Master File view, when previewing txt and xml files, line breaks were not shown. This is now solved.
- **Affected area(s):** Viedoc eTMF
Bug description: In the Trial Master File view, when downloading and previewing published documents that had multiple versions of the file, and when generating the archive when there were published documents that had multiple versions of the file, error messages were incorrectly displayed. This is now solved.
- **Affected area(s):** Viedoc Reports
Bug description: The result of the query age calculation in the Queries standard operation report was incorrectly displayed in studies that are not synced due to inactivity. This is now solved.
- **Affected area(s):** Viedoc Reports
Bug description: Certain reports in Viedoc Reports failed to load due to a set data export version for studies set in Viedoc Admin. This is now solved, as Viedoc Reports will use the latest export version for data synchronization. This will not affect data export version.
- **Affected area(s):** Viedoc Reports
Bug description: In a study with only ‘Unconfirmed missing data’ in the Queries standard operation report, the ProcessedQueries section did not list the unconfirmed missing data records. This causes ‘Missing data’ report to render empty. This has now been solved by ensuring the unconfirmed missing data records are listed in the report.
- **Affected area(s):** Viedoc Designer
Bug description: When a study with a custom report was created, and the Global design settings were published, Viedoc Reports configuration resets. This is now solved.
- **Affected area(s):** Viedoc Me
Bug description: Viedoc Me displayed the incorrect date in the “Today’s date” marker. This is now solved.
- **Affected area(s):** Viedoc Me
Bug description: When a user submitted a Japanese PDF form through Viedoc Me if that form was generated in Viedoc Clinic, the characters on the form would display incorrectly. This is now solved.

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Known limitations



List of limitations that have been found with this and earlier releases of Viedoc, and will be changed in future releases.

The following limitations exist in this release of Viedoc:

Viedoc Clinic

- CSV export
 - The export to .csv fails if the same OID was used in Viedoc Designer in different design versions with different casing (for example, an OID defined as AE in design version 1 and ae in design version 2).
 - Labels are truncated to 200 characters when CSV data is imported to SAS using the CSV2SAS macro.
 - The Excel/ CSV export does not include items set to “Hide Always” in visibility conditions when a single form is selected for export.
- Data export
 - The export preview with graph pages results in a JavaScript error on Internet Explorer 8 on some instances.
 - The export preview is not working with Safari running on Windows OS or older Safari versions running on Mac OSX.
- Data review
 - Queries of the type “Required value missing” responded with “Confirmed as missing” and cannot be rejected by the sponsor side.
 - A field that is required for SDV but is hidden on a form (due to for example visibility conditions) can normally not be marked as having been verified by SDV. Yet, if the entire form is marked as having been verified by SDV, then even hidden fields are included and marked as having been verified by SDV.
- Edit/enter data
 - For scheduled and unscheduled events, when the visit date form (\$EVENT) is excluded when you use automatic event dates, it still counts. In the signing console the counter (number of forms) for a visit includes the \$EVENT form. It cannot be selected to be signed but can be signed if you select sign all (for subject or visit). If you sign forms on a visit individually you will not be able to sign the \$EVENT form. This in turn makes it so that the sign symbol that appears on the visit when everything is signed does not appear, even though it looks like everything is signed.
 - When populating numeric fields using functions and reference data, they automatically receive the number of decimals configured in the design.
 - It is not possible to delete unscheduled visits if automatic visit dates are enabled.

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List of known limitations continues.

- File upload
 - For security reasons, it is not allowed to upload executable files. The complete list of unsupported file types can be found in Viedoc 4.34 Release Notes.
 - The upload of password-protected zip files is not supported, as Viedoc is not able to scan these files for viruses.
- Issues and task
 - The Issue list will not be visible for sites that have more than 1000 subjects.
- Layout
 - When adjusting the font size in a form item this is not respected by Internet Explorer 11. This may result in a change to the layout of the form. The descending sorting in the subject list view is not working properly.
- Medical coding
 - The Medical coding console is not working with Safari running on Windows OS or older Safari versions running on Mac OSX.
- Metrics
 - The number of open queries differs between the Queries page and the Performance page. The Performance page also includes queries with state "Removed".
- PDF export
 - Visit date form history will not be included in PDF export if no forms were filled in, or if forms were initiated from ViedocMe.
 - When using Windows 7, filenames added to the zip archive during PDF export get scrambled when they contain Unicode characters. The extracted file content is not affected by this. There is a Hotfix for Windows 7 available at: <https://support.microsoft.com/en-us/kb/2704299> that addresses this issue.
 - PDFs generated upon form save in Viedoc versions prior to 4.51 were generated and stored based on the role visibility conditions applied to the user that last saved the form. Items that were hidden to the user due to role visibility conditions are not shown/included in such generated PDFs.
 - Fully PDF/A compliant archives are only supported if all the included form PDFs and study event PDFs were generated on, or, after 2017-03-10 (Viedoc 4.33). It is still possible to generate PDF/A compliant archives that contain form and study event PDFs generated before this date, but you might receive warning messages related to PDF transparency issues.
 - In the PDF/A export output, the header, footer, and the text on the respective Contents page are missing for the deleted forms/events/subjects.

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List of known limitations continues.

- Selection page
 - The descending sorting in the subject list view is not working properly.
 - When clicking to sort a column containing dates in the subject list view, Viedoc sorts all dates using a numeric variant of US date representation (for example, 1977-NOV-16 comes before 1967-DEC-16 because the first is sorted like 11/16/1977 and the latter is sorted like 12/16/1967).
 - The event overview page is not working with Safari running on Windows OS or older Safari versions running on Mac OSX.
- Documentation and Training
 - When downloading a PDF of the Viedoc User Training Certificate, the generated PDF is limited to two pages. This means that when there are more training sections completed than can fit onto two pages, the PDF will not generate a third page and some of the training sections will be missing.

Viedoc Admin

- Apply revision
 - The affected forms count shown in Viedoc Admin while applying a study design revision is implemented only for production sites. Demo/Training site forms are not included in this count.
- Data import
 - It is only possible to import values (choice numbers), not strings (choice labels), when importing data into data fields where multiple checkboxes can be checked.
- ODM import/export
 - It is not possible to import an ODM file that was exported from Viedoc including the Event Dates into Viedoc Admin. The following error message is displayed: “An item with the same key has already been added”.
 - Only one (selected) design can be imported from each CDISC ODM file.
 - ODM export fails when subject data contains large, uploaded files.
- User management
 - Any of the Organization Administrator, Organization Designer, and Site Manager roles that were removed from a user are not listed in Viedoc Admin, under User Settings > Studies and Roles.
 - When sorting studies by group and generating a “User and Roles” or “User Administration Log” report, the Download link is not exposed for the newly generated file until the page is refreshed.

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List of known limitations continues.

- **Study Settings**
 - The Logs tab for generating the Admin audit trail report does not appear on the Study Settings page if the system language is German or Swedish.
 - The Documentation tab for the documentation and training feature, do not appear on the Study Settings page if the system language is German.

Viedoc Designer

- **Alerts**
 - If the condition for an alert is set within a form for which the option to auto-update functions is enabled, and the alert is triggered, the alert message will be sent twice.
- **Edit checks**
 - Edit checks are not triggered on dates when the event date is used as default value, and the calendar picker is used to choose the date.
 - Using \$THIS inside a form to refer to an item within a different instance of the same form, does not work, as it always refers to the same form instance. This is true when referring to an item in the same form within another activity, or when referring to another form instance within the same activity (applicable for repeating forms).
 - If two scheduled events have the same event date, and both events contain a form with a function or data check that uses the \$PREV function, the \$PREV functions in these two events refer to each other as the previous event, and not to the event that occurred earlier in the study workflow. This creates a circular reference and makes it impossible to refer to earlier event(s).
- **Form and workflow PDF**
 - If, in the Study Workflow, there are more activities with the same activity name within the same event, then the forms in these activities are incorrectly displayed in the Bookmarks list in the study workflow PDF. Please note that only the Bookmarks list is affected, the events/activities/forms are correctly displayed within the document.
 - The PDFs generated as Empty CRFs will not display all code list items for radio buttons, drop-down lists and checkboxes if these have been configured with many code list items in a vertical layout.
- **Item settings**
 - For the code list items (checkboxes, radio buttons, dropdown), it is possible to set the same code list values for multiple choices within the same item. This is not recommended. Unique code list values should be used for each of the choices within the same item.

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List of known limitations continues.

- JavaScript
 - The setMonth function with negative values is not supported. The date is not saved into the system correctly when the function is run on the server-side.
- Roles and permissions
 - If the role that has the permission for Emergency unblinding also has a role visibility condition that makes the blinded outcome hidden for this role, the outcome gets hidden for all roles after unblinding, and not just for the role specified in Viedoc Designer.
- Study workflow
 - When the Event ID for the Study Start event contains the word “START”, including combinations with other words and punctuation, and scheduling other events based on the Study Start event, this results in an error. The workaround is to use a different ID for the Study Start event, one that doesn’t contain the word “START”.
- Validation of study design
 - Validation of alerts, selection view settings, event visibility, subject status condition, common event summary format and subject ID generation settings for deleted items is not performed.
- Visibility conditions
 - When creating forms for ViedocMe, visibility conditions can only include variables that have already been introduced, and that are in the same form and on the same page. This behavior differs from the one in forms for Viedoc Clinic.

Viedoc API

- The API method SubmitData allows submitting data into a form that exists in the effective design but does not exist within the respective event according to the study workflow. In such a case, a new form is created and added to the event.

ViedocMe

- In the UI-optimized version of Viedoc Me, when a simple visibility condition has been set to make a form item show depending on the selection of a radio button, and a subject selects the radio button, an error message is displayed
- If additional languages are imported (to be used in ViedocMe) and after that code lists are combined via “Formats” (for example for SAS export) then the imported languages are lost. The workaround is to import the languages again after the code lists have been combined.
- For ViedocMe translations, if any of the translated values in the file to be imported is a number, the file import fails without prompting any feedback to the end user. The workaround is to remove the numbers from the columns in the translated file that correspond to the translated content, before importing the file in Viedoc Designer (the numeric values will be kept in the original English version and will be displayed as such in the translated ViedocMe form).

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List of known limitations continues.

- The drawing pad item is not working on IE 11. For Safari it only works on Safari 12+ versions.
- Viedoc Me does not support forms with form link items.
- The PDF export containing form PDFs submitted from the new Viedoc Me application in Japanese Kanji will not be generated correctly if embedded fonts are included.
- Long option labels for radio buttons and check boxes do not have line breaks.

Viedoc Logistics

- In the exported stock list, the audit trail shows one row for the create action for older kits. For more recently uploaded kits, the audit trail shows two rows for the create action.

Viedoc Reports

- There are some graphical limitations of the interface on mobile devices.
- Variables/fields that have an output field ID defined will be identified with this ID in the Data Browser and Reports pages, whereas they will be identified with field ID in the Dashboard, Demographics, and AE pages.
- The Overdue Events Report does not include any Viedoc Me events. Events without a proposed date are not included in this report. Events that have been planned or initiated are not included in this report, even if the planned/initiated event is outside of the event window.

Viedoc eTMF

- Viedoc eTMF is only running in Production mode.
- For security reasons, the document preview in the Trial Master File view does not support ActiveX components.
- The search for document content is disabled on the training server.

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Signoff



Signature Confirmation by
the product owner.

Uppsala, Sweden 2023-02-28

A handwritten signature in blue ink, appearing to read "Andreas Hedlund". The signature is written in a cursive style and is positioned above a horizontal line.

Andreas Hedlund

Viedoc Technologies